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EXAMINER	
BAUSCH, SARAE L	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,044	MILLER ET AL.	
	Examiner	Art Unit	
	Sarae Bausch PhD	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25,27-37,42,44-61,67 and 68* is/are pending in the application.

4a) Of the above claim(s) *29-36 43-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25,27,28,37,42,67 and 68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Currently, claims 1-25, 27-37, 42, 44-61, 67-68 are pending in the instant application. Claims 29-36, 44-61 have been withdrawn from consideration as being drawn to a nonelected invention. Claims 67-68 are newly added. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. The following rejections are either newly presented, as necessitated by amendment, or are reiterated from the previous office action. Any rejection not reiterated is withdrawn, necessitated by the amendment to the claims. Response to arguments follow. This action is Final.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-11, 14-21, 24, 27-28 and 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cass et al. (US Patent 6312906, cited on IDS) in view of Herne et al. (J Am Chem Soc, 1997, 119:8916-8920).

Cass et al. teach a device that comprises a solid phase surface comprising a material that quenches fluorescence (fluorescence quenching surface), a self complementary single stranded oligonucleotide probe linked to the solid surface and the probe comprising a fluorophore attached to the other end (see column 3 lines 42-50 and claim 27). Cass et al. teach modification of the oligonucleotide probe to attach to the solid surface (see column 10 lines 10-50). Cass does not teach a plurality of spacer molecules that when mixed has a ratio of 5:1 or greater nor exemplify a sensor chip that has a 5 fold increase in fluorescence intensity when expose to a target.

With regard to claim 2-4, Cass et al. teach the fluorescence surface quenching area of the sheet or in pattern such as dots or lines (substantially entire substrate and plurality of discrete locations) (see columns 9 lines 34-50 and column 13 lines 6-15).

With regard to claims 5-8, Cass et al. teach solid surface that comprise gold, silver, and quartz doped with transition metal (see column 9 lines 10-20). Cass teaches that solid phases can be semiconductors such as N type or P type doped material (See column 15 lines 30-40 and claim 18).

With regard to claim 9-11 and 42, Cass et al. teach fluorophores that are rhodamine dyes as well as phycobilliproteins (see column 8, lines 32-48).

With regard to claim 14-16 and 38-40, Cass et al. teach the nucleic acid can be RNA, DNA or PNA (see figure 4 and column 6 lines 60-65).

With regard to claim 17, Cass et al. teach at least 6-12 contiguous nucleotides complementary to the nucleic acid (see column 6 lines 45-50 and column 17 lines 1-5).

With regard to claims 18-21 and 24,Cass et al. teach individual species of probes (one or more additional nucleic acids that are different) are immobilized on solid support that has a set of discrete and isolated regions on a substrate (bound to first and second discrete locations) (See column 13 lines 25-67).

With regard to claims 26-28, Cass et al. teach variable length spacers attached to the end of oligonucleotides. Additionally, Cass et al. teach mixing long chain amino alcohols to intersperse DNA which results in attachment of oligonucleotides down to 50nm apart on the surface (see column 10, lines 20-38).

With regard to claims 41, Cass et al. teach thiol modified oligonucleotides (thiol modified base) (see column 10 lines 38-48).

However, Herne et al. teach characterization of DNA probes immobilized on gold surfaces. Herne et al. teach gold substrate exposure to both DNA and mercaptohexanol (MCH) to remove nonspecifically absorbed DNA from the gold surface (See abstract). Herne exemplifies in figure 4B a ratio of 5:1 MCH:DNA on a gold surface. Herne further teaches that optimal concentration and exposure for MCH:DNA was sample 8 (see pg. 8920, 1st column, 2nd paragraph) and teach that sample 8 when hybridized to its complementary DNA has an increase in intensity of over 100 (see sample 1 vs. sample 8) therefore Herne teaches that a ratio of 5:1 of MCH to DNA yields an increase in signal strength. Herne teaches that MCH controlling the surface coverage of DNA is an important factor in maximizing hybridization efficiency (see pg. 8920, 2nd column).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used an MCH on DNA immobilized on gold surface, as taught by Herne, in the oligonucleotide hairpin probe bound to a solid surface comprising gold as taught Cass. One would have been motivated to use MCH and a ratio of MCH to DNA that would enhance the hybridization efficiency that would enhance the intensity of the detected signal based on the teachings of Herne that MCH immobilized on the surface with DNA yields optimal hybridization efficiency, as well as by the teachings of Cass that the density of nucleic acids to gold and platinum surfaces is controlled by use of defined mixtures of mono and dithiols. One would have had a reasonable expectation of success because Cass teaches attaching DNA to gold surfaces, as well as control of density of DNA attachment and Herne exemplifies a thiol, MCH, a conditions that allow for increased hybridization efficiency which increases the detection intensity by several fold. Therefore the skilled artisan would have expected that the use of MCH as taught by Herne with the DNA immobilized sensor chip of Cass would have yielded the predictable result of increased fluorescence intensity detection at a rate greater than 20 fold, as exemplified by Herne. Additionally, because both Cass et al. and Herne et al. teach immobilized DNA to gold surface and the use of thiols, it would have obvious to one skilled in the art to substitute known elements, thiol of Cass for MCH in order to achieve the predictable result of higher hybridization efficiency and thus greater detection and signal strength.

5. Claims 12-13 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cass et al. (US Patent 6312906, cited on IDS) in view of Herne and further in view of Bruchez et al. (US 2002/0034747).

Cass in view of Herne is set forth above. Cass in view of Herne does not teach semiconductor nanocrystals attached to the nucleic acid probe nor does Cass teach that two different fluorophores that are different.

Bruchez et al. teaches the use of semiconductor nanocrystal labels attached to different polynucleotides to allow for simultaneous analysis of multiple polynucleotides (see para 16 and para 42-43). Bruchez et al. teaches a semiconductor nanocrystal attached to a probe which can be a molecular beacon (see para 13 and figure 1A). Bruchez et al. teaches a semiconductor nanocrystal comprises a core and shell that is a semiconductor material (See para 59 and 61) (claims 12-13). Bruchez et al. teaches using more than one semiconductor nanocrystal that has at least one different fluorescence characteristic, including emission spectra (see para 83).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the nucleic acid probe attached to a quenching surface and fluorophore by Cass et al. in view of Herne to include different fluorophores, including different semiconductor nanocrystal fluorophores, as taught by Bruchez, to improve the nucleic acid probe of Cass in view of Herne and allow for more versatility in fluorescence. The ordinary artisan would have been motivated to improve the type of fluorophore attached to the nucleic acid of Cass et al. in view of Herne to include the semiconductor nanocrystal of Bruchez because Bruchez teaches that the nanocrystals allow for multiplexing of detection of different nucleic acids, using different emission wavelengths, and allows for higher assay throughput, decreased cross contamination resulting in more reliable results as well real time monitoring (see para 17). The ordinary artisan would have had a reasonable expectation of success that the use of semiconductor nanocrystals could be used as fluorophores in the nucleic acid probes taught by

Cass et al. in view of Herne because both Cass et al. and Bruchez et al. teach molecular beacon probes that form hairpin structures with a fluorophore on one end of the probe and a quencher on the other end. Additionally, because both Cass et al. and Bruchez et al. teach molecular beach probes with fluorophores and quenchers attached to the nucleic acid probe, it would have obvious to one skilled in the art to substitute known elements, semiconductor nanocrystals as taught by Bruchez for the fluorescent dye as taught by Cassin view of Herne in order to achieve the predictable result of higher assay throughput.

6. Claims 37, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cass et al. (US Patent 6312906, cited on IDS) in view of Vannuffel et al. (J. Clin. Microbiology, 1995, vol. 33, pp. 2864-2867), Berger-Bachi et al. (GenBank accession No. X17688, gi 46579) and Hogan et al. (US Pat. 5,541,308, July 30, 1996).

Cass et al. teach a device that comprises a solid phase surface comprising a material that quenches fluorescence (fluorescence quenching surface), a self complementary single stranded oligonucleotide probe linked to the solid surface and the probe comprising a fluorophore attached to the other end (see column 3 lines 42-50 and claim 27). Cass et al. teach modification of the oligonucleotide probe to attach to the solid surface (see column 10 lines 10-50). Cass does not teach SEQ ID NO: 1.

Vannuffel teach detection of methicillin resistant staphylococcus by multiplex PCR by detection of the FemA gene (see abstract). Vannuffel teaches four different oligonucleotide probes that detect and are complementary to the FemA gene (see oligonucleotides, pg. 2865) as taught by Berger-Bachi et al. Vannuffel teaches that multiplex PCR for the FemA gene allows for rapid and specific identification of resistance patterns and pathogens (see pg. 2867, last para).

Vannuffell teaches detection of femA has a high level sensitivity 100% and teaches that FemA is unique to S. aureus which allows for specific detection (see pg. 2867, 1st para). Thus, Vannuffell teaches that detection of FemA gene allows for specific species identification of S. aureus with high sensitivity.

Berger-Bachi et al. teaches the entire sequence of the FemA gene, GenBank accession number X17688, which comprises nucleotides 700 to 731 which are identical to nucleotides 10-41 of SEQ ID NO: 1.

Additionally, Hogan et al. (herein referred to as Hogan) teaches the use of specific probes col. 6-7, lines 50-67, lines 1-12, and furthermore provides specific guidance for the selection of probes,

> "Once the variable regions are identified, the sequences are aligned to reveal areas of maximum homology or 'match'. At this point, the sequences are examined to identify potential probe regions. Two important objectives in designing a probe are to maximize homology to the target sequence(s) (greater than 90% homology is recommended) and to minimize homology to non-target sequence(s) (less than 90% homology to non-targets is recommended). We have identified the following useful guidelines for designing probes with the desired characteristics.
> First, probes should be positioned so as to minimize the stability of the probe:nontarget nucleic acid hybrid. This may be accomplished by minimizing the length of perfect complementarity to non-target organisms, avoiding G and C rich regions of homology to non-target sequences, and by positioning the probe to span as many destabilizing mismatches as possible (for example, dG:rU base pairs are less destabilizing than some others). Second, the stability of the probe:target nucleic acid hybrid should be maximized. This may be accomplished by avoiding long A and T rich sequences, by terminating the hybrids with G:C base pairs and by designing the probe with an appropriate Tm. The beginning and end points of the probe should be chosen so that the length and %G and %C result in a Tm about 2-10°C higher than the temperature at which the final assay will be performed. The importance and effect of various assay conditions will be explained further herein. Third, regions of the rRNA which are known to form strong structures inhibitory to hybridization are less preferred. Finally, probes with extensive self complementarity should be avoided."

Hogan teaches that "while oligonucleotide probes of different lengths and base composition may be used, oligonucleotide probes preferred in this invention are between about 15 and about 50 bases in length" (col. 10, lines 13-15). Oligonucleotides complementary to sequences adjacent to the probe regions were synthesized and used in the hybridization mix according to Hogan et al.,U.S. Pat. No. 5,030,557., filed Nov. 24, 1987, entitled "Means and Method for Enhancing Nucleic Acid Hybridization (the "helper " patent application). Hogan teaches that oligonucleotide probes may be labeled by any of several well known methods such as radioisotopes, non-radioactive reporting groups, non-isotopic materials such as fluorescent molecules (col. 10, lines 45-60). Hogan teaches that probes may be labeled using a variety of labels, as described within, and may be incorporated into diagnostic kits.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the nucleic acid probes taught by Cass et al. to include a probe to detect FemA gene as taught by Vannuffel and the sequence taught by Berger-Bachi et al. to allow for detection of S. aureus. The ordinary artisan would have been motivated to improve the nucleic acid probes taught by Cass et al. with a probe target sequence specific for FemA as taught by Vannuffel and Berger-Bachi because Vannuffel teaches detection of FemA gene allows for a sensitive and specific assay for methicillin resistant S. aureus . The ordinary artisan would have had a reasonable expectation of success that the use of hairpin loop, including a stem loop structure and target region, as taught by Cass et al. to include a sequence that is specific for FemA because both Vannuffell and Berger-Bachi teach the sequence of the FemA and specificity of detecting FemA gene and Cass et al. teaches that nucleic acid probes allow for simultaneous detection of multiple nucleic acid species from the same sample.

Additionally, designing probes which are equivalents to those taught in the art is routine experimentation. The prior art teaches the parameters and objectives involved in the selection of oligonucleotides that function as probes and primers, see Hogan et al. and Cass et al. Moreover there are many internet web sites that provide free downloadable software to aid in the selection of probes drawn from genetic data recorded in a spreadsheet. The prior art is replete with guidance and information necessary to permit the ordinary artisan in the field of nucleic acid detection to design probes. As discussed above, the ordinary artisan would be motivated to have designed and test new molecular beacon probes to obtain additional oligonucleotides that function to detect FemA gene and identify oligonucleotides with improved properties. The ordinary artisan would have a reasonable expectation of success of obtaining additional probes from within the alignment provided by Berger-Bach, including a stem loop of 6 to 10 complementary nucleotides to allow for the detection of the FemA gene using molecular beacon probes features taught by Cass. Thus, for the reasons provided above, the ordinary artisan would have designed additional probes, including a probe with the SEQ ID NO 1 using the teachings in the art at the time the invention was made.

Response to Arguments

7. The response traverses the rejection with respect to claim 43, now claim 37. The response asserts that none of the references teaches or suggest the specific probes recited and assert that thousands of different probes could be formed and Vannuffell only identifies two of them. The response asserts that given the thousands of possibilities applicant asserts that the mere knowledge of the femA sequence and general methods of probe design is insufficient to demonstrate obviousness of the claimed probes. This response has been thoroughly reviewed but

not found persuasive. The number of possible probes that are generated from the femA sequence is a finite number and each probe of the femA sequence would function to detect femA in a predictable manner with reasonable expectation of success. Thus a person of ordinary skill would have good reason to pursue known options within his or her technical grasp and would lead to anticipated success, as demonstrated by the art on probe and primer design. Thus in the instant case the shear number of the probes does not make the invention non-obviousness as although there may be thousand of possible probes each probe is expected to function in a predictable manner, as demonstrated in the art. Additionally the prior art gives an indication of which parameters are necessary for generating probes and provides guidance on generating probes to detect the femA gene, thus the ordinary artisan would have generated probes to detect the femA gene including SEQ ID NO 1.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

8. Claims 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cass et al. (US Patent 6312906, cited on IDS) in view of Herne and further in view of Vannuffel et al. (J. Clin. Microbiology, 1995, vol. 33, pp. 2864-2867), Berger-Bachi et al. (GenBank accession No. X17688, gi 46579) and Hogan et al. (US Pat. 5,541,308, July 30, 1996).

Cass et al. in view of Herne is set forth above. Cass et al. in view of Herne teach modification of the oligonucleotide probe to attach to the solid surface (see column 10 lines 10-50). Cass in view of Herne does not teach SEQ ID NO: 1.

Vannuffel teach detection of methicillin resistant staphylococcus by multiplex PCR by detection of the FemA gene (see abstract). Vannuffel teaches four different oligonucleotide probes that detect and are complementary to the FemA gene (see oligonucleotides, pg. 2865) as taught by Berger-Bachi et al. Vannuffel teaches that multiplex PCR for the FemA gene allows for rapid and specific identification of resistance patterns and pathogens (see pg. 2867, last para). Vannuffell teaches detection of femA has a high level sensitivity 100% and teaches that FemA is unique to S. aureus which allows for specific detection (see pg. 2867, 1st para). Thus, Vannuffell teaches that detection of FemA gene allows for specific species identification of S. aureus with high sensitivity.

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> First, probes should be positioned so as to minimize the stability of the probe:nontarget nucleic acid hybrid. This may be accomplished by minimizing the length of perfect complementarity to non-target organisms, avoiding G and C rich regions of homology to non-target sequences, and by positioning the probe to span as many destabilizing mismatches as possible (for example, dG:rU base pairs are less destabilizing than some others). Second, the stability of the probe:target nucleic acid hybrid should be maximized. This may be accomplished by avoiding long A and T rich sequences, by

> terminating the hybrids with G:C base pairs and by designing the probe with an appropriate Tm. The beginning and end points of the probe should be chosen so that the length and %G and %C result in a Tm about 2-10°C higher than the temperature at which the final assay will be performed. The importance and effect of various assay conditions will be explained further herein. Third, regions of the rRNA which are known to form strong structures inhibitory to hybridization are less preferred. Finally, probes with extensive self complementarity should be avoided."

Hogan teaches that "while oligonucleotide probes of different lengths and base composition may be used, oligonucleotide probes preferred in this invention are between about 15 and about 50 bases in length" (col. 10, lines l3-15). Oligonucleotides complementary to sequences adjacent to the probe regions were synthesized and used in the hybridization mix according to Hogan et al.,U.S. Pat. No. 5,030,557., filed Nov. 24, 1987, entitled "Means and Method for Enhancing Nucleic Acid Hybridization (the "helper " patent application). Hogan teaches that oligonucleotide probes may be labeled by any of several well known methods such as radioisotopes, non-radioactive reporting groups, non-isotopic materials such as fluorescent molecules (col. 10, lines 45-60). Hogan teaches that probes may be labeled using a variety of labels, as described within, and may be incorporated into diagnostic kits.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the nucleic acid probes taught by Cass et al. in view of Herne to include a probe to detect FemA gene as taught by Vannuffel and the sequence taught by Berger-Bachi et al. to allow for detection of S. aureus. The ordinary artisan would have been motivated to improve the nucleic acid probes taught by Cass et al. in view of Herne with a probe target sequence specific for FemA as taught by Vannuffel and Berger-Bachi because Vannuffel teaches detection of FemA gene allows for a sensitive and specific assay for methicillin resistant S. aureus . The ordinary artisan would have had a reasonable expectation of success that the use

of hairpin loop, including a stem loop structure and target region, as taught by Cass et al. in view of Herne to include a sequence that is specific for FemA because both Vannuffell and Berger-Bachi teach the sequence of the FemA and specificity of detecting FemA gene and Cass et al. in view of Herne teaches that nucleic acid probes allow for simultaneous detection of multiple nucleic acid species from the same sample.

Additionally, designing probes which are equivalents to those taught in the art is routine experimentation. The prior art teaches the parameters and objectives involved in the selection of oligonucleotides that function as probes and primers, see Hogan et al. and Cass et al in view of Herne. Moreover there are many internet web sites that provide free downloadable software to aid in the selection of probes drawn from genetic data recorded in a spreadsheet. The prior art is replete with guidance and information necessary to permit the ordinary artisan in the field of nucleic acid detection to design probes. As discussed above, the ordinary artisan would be motivated to have designed and test new molecular beacon probes to obtain additional oligonucleotides that function to detect FemA gene and identify oligonucleotides with improved properties. The ordinary artisan would have a reasonable expectation of success of obtaining additional probes from within the alignment provided by Berger-Bach, including a stem loop of 6 to 10 complementary nucleotides to allow for the detection of the FemA gene using molecular beacon probes features taught by Cass in view of Herne. Thus, for the reasons provided above, the ordinary artisan would have designed additional probes, including a probe with the SEQ ID NO 1 using the teachings in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-25, 27-28, 37, 42, 67-68 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 11/838616. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 1 is generic to all that is recited in claim 7 of '616 and instant claim 37 is generic to all that is recited in claim 1 of '616. Claims 2-6 and 8-14 of '616 fall entirely in the scope of instant claims 2-28 and 38-43.

Specifically the sensor chip comprising a quenching surface and a first nucleic acid that hybridizes to Staphylococcus, a first fluorophore tethered to the first end of the nucleic acid of '616 anticipates the genus of a sensor chip comprising a quenching surface, a first nucleic acid that has a first fluorophore attached to the first end and a second region that is able to hybridize to the first region in the instant application. Furthermore, fluorescence quenching surfaces, fluorophores, and semiconductor metals of the instant application is disclosed in '616

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-25, 27-28, 37, 42, 67-68 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 11, 13-14, 17-21 of U.S. Patent No. 7442510 (US Patent Application 11/553904). Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 1 is generic to all that is recited in claim 1 of '510. Claims 2-8, 13-14, 17-21 of '510 fall entirely in the scope of instant claims 2-28.

Specifically the isolated nucleic acid comprising a hairpin DNA molecule that hybridizes over its full length to a target nucleic acid that has a naturally occurring sequence, label tethered to one terminus of the hairpin molecule and a quenching agent tethered to the other terminus of '510 anticipates a sensor chip comprising a fluorescence quenching surface and a first nucleic acid molecule with a first region complementary to a second region wherein the first end bound to the quenching surface and the second end bound to a fluorophore of instant claim 1. Additionally, SEQ ID NO. 1 of instant claim 25 is a sequence of FemA gene from S. Aureus, which is a naturally occurring sequence. Furthermore solid surfaces, quenching agents that are metal, fluorescent label that are dyes of the instant application are disclosed in '510 (specifically claims 2-8).

11. Claims 37 and 42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 11, 13-14, 17-21 of U.S. Patent No. 7442510 (US Patent application 11/553904) in view of Cass et al. (US Patent 6312906) and Herne. Although the conflicting claims are not identical, they are not patentably distinct from each other

because claim 1 of '510 is drawn to an isolated nucleic acid probe comprising a hairpin, a label tethered to one terminus and a quenching agent tethered to the other terminus while instant claim 37 comprises a nucleic acid probes comprising a first end being modified for coupling to a surface and second end being bound to a fluorophore. Claim 1 of '510 does not recite a first end being modified for coupling to a surface, however Cass et al. teaches attachment of a quenching surface to a nucleic acid molecule via a modified end of a nucleic acid (see column 10 lines 38-48). Therefore, the modified end of the instantly claimed invention encompasses the nucleic acid probe of '510. Additionally, SEQ ID NO. 1 of instant claim 43 is a sequence of FemA gene from S. Aureus, which is a naturally occurring sequence. Furthermore fluorescent label that are dyes of the instant application are disclosed in '510 (specifically claims 2-8).

Response to Arguments

12. The response traversese the rejections. The response asserts that neither '616 nor '510 claim a plurality of spacer molecules with a ratio of 5:1 or exhibit a 5 fold increase. However this response has been thoroughly reviewed but not found persuasive. The portions of the specification of '616 that support the claimed sensor chip teach a ratio of 5:1 spacer molecule and a fluorescence intensity of 5 fold (see example 2 of '616 and para 54 and ex 7 of '904), therefore the claims in the light of the specification of '616 and '904 are not patentably distinct from the instant invention.

Conclusion

13. No claims are allowable.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Sarae Bausch/
Primary Examiner, Art Unit 1634